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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,449	03/24/2004	Karin Jooss	3802-090-27 CIP	3354
29585	7590	03/04/2009		
DLA PIPER US LLP 153 TOWNSEND STREET SUITE 800 SAN FRANCISCO, CA 94107-1957			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 03/04/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/807,449	<b>Applicant(s)</b> JOOSS ET AL.	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-43 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,9,12-18,21,22 and 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-8,10,11,19,20,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 11/25/2008 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/25/2008 has been entered.

Claims 1 and 3 – 43 are pending.

Claims 3, 5, 9, 12 – 18, 21 – 22, and 25 – 43 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 11/21/2006.

***Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 are presently under consideration, as they read on the elected invention and species.***

2. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

3. Claims 1, 6 – 8, 11, 19 – 20, and 23 – 24 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6 – 8, 11, 19 – 20, and 23 – 24 are indefinite in the recitation of “bystander cells” in the context of the instant claims. One of skill in the art is aware that in the context of therapy, bystander cells are the cells of the patient to which the therapy is not directed, but which are nonetheless affected by the therapy. In the instant claims, bystander cells appear to be used as the therapeutic substance, which appears to be inconsistent with the common usage of the term in the art. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

4. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

*(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

5. Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 stand rejected under **35 U.S.C. 102(a) and 102(e)** as being anticipated by Chen et al. (US Pat. Pub. No. 2003/0035790), for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that amendment to the claims to require that the cells of the cellular vaccine be selected from allogeneic cells and bystander cells renders the claims distinct from the teachings of the prior art.

In response, the use of the term "bystander cell" appears to be inconsistent with its conventional usage in the art, as addressed in section 3 supra.

The term "allogeneic cells" refers to cells which are genetically distinct from those of the patient, i.e. any cells from a different individual. Chen et al. explicitly teach that cells used in their therapeutic methods may be obtained from umbilical cord blood or fetal liver (e.g. paragraph 0306), i.e. a source external to the patient. As such, these cells are allogeneic, and thus within the scope of the instant claims.

Applicant further argues that Chen et al. allegedly do not teach or suggest the claimed feature of the present invention, wherein the combination therapy results in an enhanced therapeutic efficacy relative to monotherapy.

This is not found persuasive, for at least two reasons. First, Chen et al. review various monotherapies of cancer in paragraph 0005 – 0015, and then state that their invention provides combination therapy for cancer which provides "a better therapeutic effect than currently existing clinical therapies" (paragraph 0016). Second, as addressed above and in previous Office Actions, the prior art reference teaches a

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method which is manipulatively the same as instantly recited, in that it comprises the same method steps, ingredients, and patient population. Therefore, the outcome of performing the method steps are inherently the same as instantly recited.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims, and is incorporated by reference herein as if reiterated in full.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 4, 6 – 8, 10 – 11, 19 – 20, and 23 – 24 stand provisionally rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 1 – 33 of copending Application USSN 10/404,662, for the reasons of record.

Applicant's request that this rejection be held in abeyance is acknowledged.

The rejection is presently maintained for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**8. Conclusion: no claim is allowed.**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/

ILIA OUSPENSKI, Ph.D.  
Primary Examiner  
Art Unit 1644

February 26, 2009